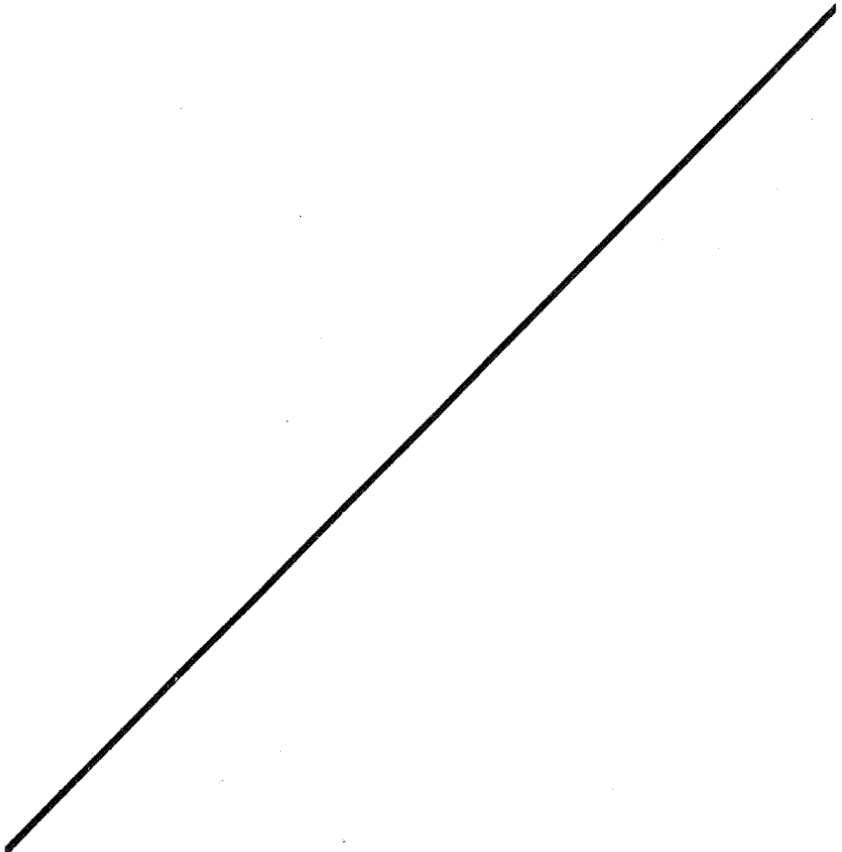


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A SURVEY OF  
in vivo ENERGY SOURCES

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## A SURVEY OF *in vivo* ENERGY SOURCES\*

### ABSTRACT

Recent engineering advances in medicine have permitted the application of various prostheses for the correction of physiological defects. Such devices as cardiac pacemakers, diaphragm stimulators, and artificial limbs have been greatly improved in effectiveness. Long term implants of electronic gadgetry have also become relatively commonplace in the biomedical community as a means for measuring several physiological parameters *in situ*. In both cases cited above, the power supply plays a vital role--because of its impact on the volume and life of the device. Although miniature batteries are doing an effective job in these applications, their two- or three-year life requires surgical procedure for replacement. To reduce this, other energy sources are being investigated. One approach is to use the body during its normal functioning to drive an electric power source. Bioelectric potentials, muscle motions, and implanted fuel cells are some of the approaches being investigated with varying degrees of success. (Another approach is to transmit the power through the skin by inductive coupling or in the form of radio frequency energy. This technique relieves the problems of battery life since the power pack is external and can be easily replaced.)

### I. INTRODUCTION

It is becoming increasingly obvious that the long range goal of extending man's span of healthy life will be resolved only after a more basic understanding of the body and its multitude of chemical/physical and physiological reactions is gained.

In order to get this fundamental knowledge, the methods and instruments of the physical sciences must be used. These, when coupled with the knowledge from medical sciences will result in measurements from which meaningful judgements can be made.

One is the measurement of electric activity within the body. For years recordings of the EKG and EEG have been made and analyzed. Electromyography is an equivalent measurement for musculature. The firing of nerves, the polarity reversal of cells, the possible piezoelectric activity of the bone call attention to the fact that the body

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\*The author's work on *Bioelectric Potentials* was supported in part by NASA Contract NAS 2-1420.

is a system of electric generators that is self-controlled and maintained. It behooves man to make effective use of this untapped source of energy.

If the requirements are for less than one milliwatt (mw) it would appear ideal to power devices by the electric energy generated within the body. Several approaches have been taken to use the body as the source of power for implanted electronic devices. These include bioelectric potentials, motion conversion to electricity, and implanted fuel cells. This paper will discuss the available information in each of these areas and attempt a ranking of approaches as a function of the state-of-the-art.

If the demand is for power levels in the range of one or more watts (artificial ventricular pumps or hearts) then the transmission of energy through the skin is an approach having merit. The techniques being investigated for this include RF energy transmission and inductive coupling.

## II. BIOELECTRIC POTENTIALS

It has long been known that an electric current can be measured by implanting a pair of dissimilar metallic electrodes in various anatomical locations. Unfortunately, the precise reason for the production of this electricity is unknown, although several hypotheses have been presented to explain this source of energy. One is that the electrode pair is simply a galvanic battery using body fluids as the electrolyte. Another hypothesis suggests that the action is solely fuel cell in nature, wherein the body metabolites serve as the fuel, and the electrodes function only to catalyze the reactions. A third theory is that there is a combination of a catalytic and a galvanic effect. It would appear, based on experiments conducted in the author's laboratory as well as elsewhere, that the source of energy is in reality a combination of a catalytic and a galvanic effect. The electrode pair acts as an oxidation reduction cell in which dissolved oxygen is catalytically reduced on a catalytically active cathode and the metallic anode oxidized. In this way, the anode is losing weight slowly, which is in effect a galvanic system. Hence the combined source for the nature of the energy production.

If one considers the galvanic theory in combination with an oxidation reduction process it would appear that an ideal location might be the stomach. The chemical gradient within the stomach is as great as can probably be found anywhere within the body. The potentials that exist between the mucosa and the serosa of the stomach (which are thought to be in some way connected to the stomach's production of hydrochloric acid) have been investigated. An energy equivalent of approximately nine microwatts per square centimeter of stomach tissue area was measured in dogs by Rehm (1948). However, the installation of a permanent electrode within the stomach would be expected to present a problem in tissue reaction similar to "hardware disease" in cattle. For this reason, the stomach as well as other vital organs such as the liver and brain have not been seriously considered as suitable electrode sites for long term implantation.

There are several conditions which must be met before bio-electric potentials may be used to power electronic gadgetry. The first and the most important is that the implantation of the electrodes must not in any way disturb the normal functioning of the host animal. This, of course, also implies that the electrode material must be such as to react very slowly with the interstitial fluids in order that excessive quantities of possibly toxic material are not produced to enter into the normal flow of materials within the body. Another vital point is that the electrodes must be quite small when compared with the host animal. Again, this could also be inferred from the first specification inasmuch as relatively large electrodes would cause some discomfort or other problem to the host. Still a fourth specification must be that the implanted electrodes should not be located within any of the major organs because of the possibility of physiological damage.

Several independent investigations have been conducted in which metallic electrodes have been inserted in the body to produce an electromotive force (emf). Pinneo and Kesselman (1959) reported that they have been able to power a specially designed FM transmitter by inserting two steel electrodes into the brain of a cat. The power output was measured at 40 millivolts and 0.5 microamps. This particular study, although pioneering in the direct application of bioelectric potentials, obviously could not be applied to long term implants, and indeed the work reported by the investigators was intended for short term.

More detailed studies of bio-electric potentials have been reported upon by Reynolds (1964), Konikoff (1964, 1966), and Roy and Wehnert (1966).

Konikoff and Reynolds (1962), extending their studies of biochemical fuel cells for the whole animal, considered the body as a container of electrolytes, numerous semi-permeable membranes, and different tissues which metabolize differently, permitting chemical gradients to exist. Under these conditions it only becomes necessary to add a catalytic agent and an electron collector (electrode) to construct a "living fuel cell." Reynolds (1964) further reported on this activity. His work began with the construction of an electrode made by sandwiching a thin film of platinum black between two screens of platinum gauze. The other electrode was a platinum screen. These electrodes were placed in an anesthetized rat and the open circuit voltage was recorded as obtained in various areas of the body. Sites such as intestine, rectum, abdominal cavity and the subcutaneous region were tested in pairs. For example, the platinum platinum black (PPB) was placed in the intestine and the platinum screen in the abdominal cavity. Electrical measurements were obtained and the electrodes were then reversed and the procedure repeated. Polarization curves showed that an optimum output was obtained when the platinum was placed subcutaneously and the PPB in the abdominal cavity. A number of electrode materials were tested and resulted in varying outputs as a function of the materials. In all cases, it was the intention to select materials that would be relatively benign. Although this held the output to comparatively low values, the possible effect of toxic by-products being formed on the electrode surface as a result of a galvanic action was minimized. Under these conditions, it was determined that the best output resulted from an electrode pair made of platinum platinum black (PPB) and high speed stainless steel (HSS), Figure 1. It was also

# OPTIMUM ELECTRODE SYSTEM

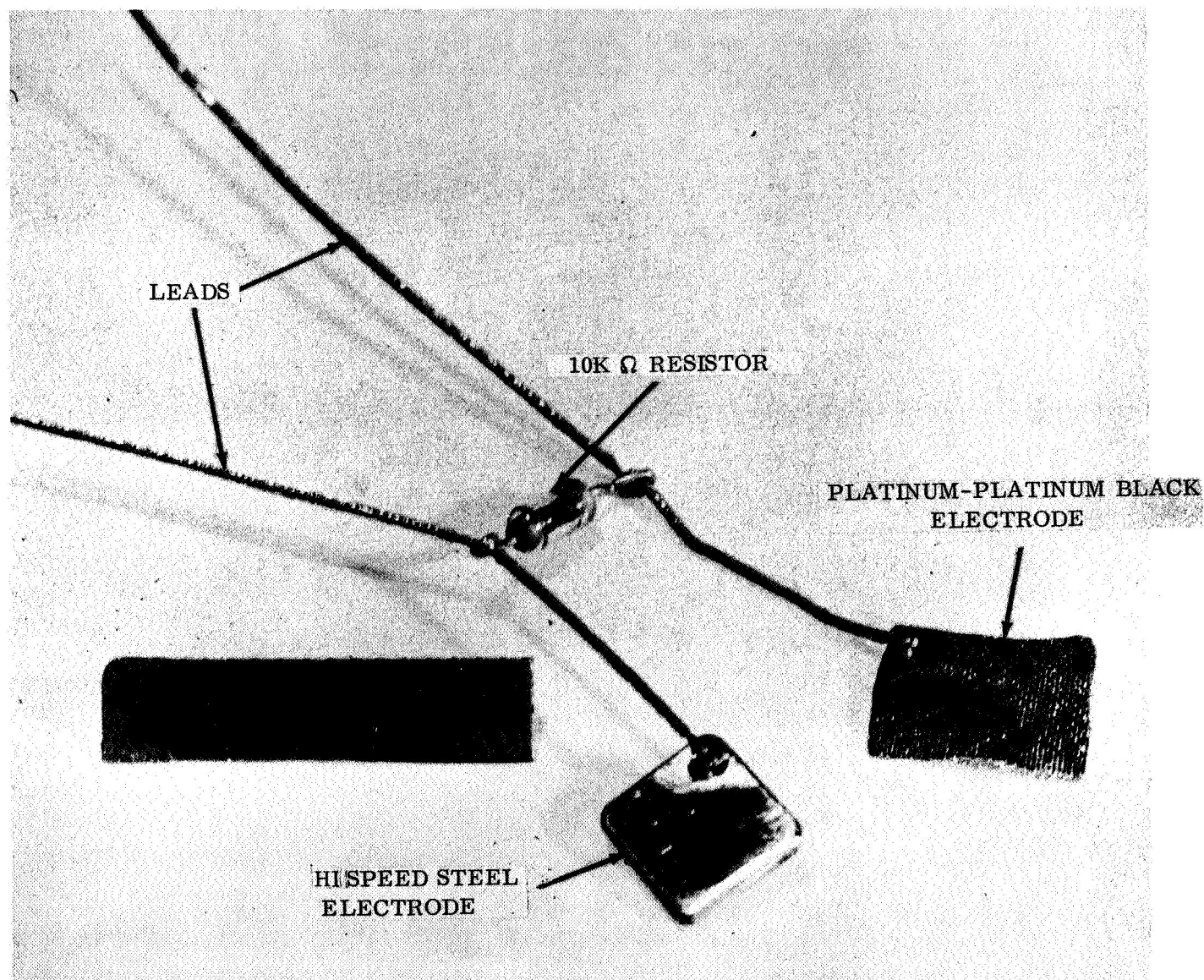


FIGURE 1

determined that the abdominal cavity appeared to be the optimal anatomical site for the implant of the PPB electrode, with the HSS located subcutaneously. This is of great importance because this area is large enough to accommodate the electrodes and no vital biological activities are disturbed.

Konikoff (1964, 1966) continued this research, and by standardizing the measurement techniques was able to draw firm conclusions about the output as a function of electrode material. It was determined that the optimum material combination was platinum platinum black and high speed stainless steel. Studies were also conducted to determine the output versus anatomical location, and it was determined that from surgical ease, space availability, and the fact that no vital organs were disturbed, the peritoneal cavity appeared to be the best location. Additional studies resulted in defining the effect of electrode size on the output. It was shown that by increasing the PPB electrode an appreciable increase in output was achieved. Over 300 microwatts resulted from a PPB electrode having a surface area of 20.5 sq. cm. The HSS electrode used had a surface area of approximately 1.5 sq. cm. This power output was measured in a 1,000 ohm resistance load at a voltage level of 0.555 (see Table I). Long term implant studies on animals were also conducted and indicated that the output became essentially constant fifteen days following surgery and remained at this constant level for a period of 128 days. For this experiment, a rabbit was used. A multiple wafer PPB (area about 10 sq. cm.) was surgically tied to the peritoneal sheath within the peritoneal cavity and the HSS electrode with an area of approximately 2 sq. cm. was positioned between the obliquus externus and obliquus internus. A 10,000 ohm resistance was connected in parallel to the electrode system, thus causing a constant power drain, Figure 2. The rabbit was permitted the relative freedom of his cage and appeared to be completely normal following the usual post-operative recovery period. Voltage readings were taken every three days and fluctuated between 0.49V and 0.50V. Under these conditions, the power was 24 microwatts ( $\mu$ w). At the end of the experiment the circuit was removed and the electrodes examined for surface discoloration or other effects which could indicate interaction with the host animal. No signs of such activity were noted. Gross examination of the tissue in the vicinity of the electrode locations showed no reactions.

Both Reynolds and Konikoff individually conducted application studies of the power available from the implantations. A 500 kilohertz (kHz) oscillator was designed to operate on an input of 50 microamps at 0.25 volts, or a 12.5 microwatt power input. A receiver equipped with a loud speaker was set on the other side of the laboratory and received a clear signal when tuned to 500 kHz. The system itself was completely powered by the animal and was stable during the eight hour experiment. A second application study was conducted by using a specially designed modulated transmitter. This device oscillated at 4.8 megahertz (mHz). An eight hour experiment was successfully concluded in which the heart-beat of the animal was transmitted to a radio receiver located thirty to forty feet distant from the animal. The sole source of power to the specially designed transmitter was the bioelectric potential derived from a rat.

# POLARIZATION DATA

ELECTRODE SURFACE AREA VS OUTPUT\*  
BIOELECTRIC POTENTIALS

Pt-Pt-B1 Surface Area Cm <sup>2</sup>	Voltage at			$\mu$ Amps at			$\mu$ Watts (Power) at		
	10K $\Omega$	5K $\Omega$	1K $\Omega$	10K $\Omega$	5K $\Omega$	1K $\Omega$	10K $\Omega$	5K $\Omega$	1K $\Omega$
1.5 (1x)	0.46	0.19	0.06	46	38	60	21.2	7.2	3.6
12.0 (8x)	0.70	0.65	0.46	70	130	460	49	84	211
20.5 (14x)	0.76	0.725	0.555	76	145	555	57.8	103	308

\*Against a 2.0 Cm<sup>2</sup> high-speed steel electrode implanted beneath the dermis and dorsad to the fascia; a new PPB made for this test was located between the external oblique and the fascia.

TABLE I

# PPB WAFER ELECTRODE SYSTEM

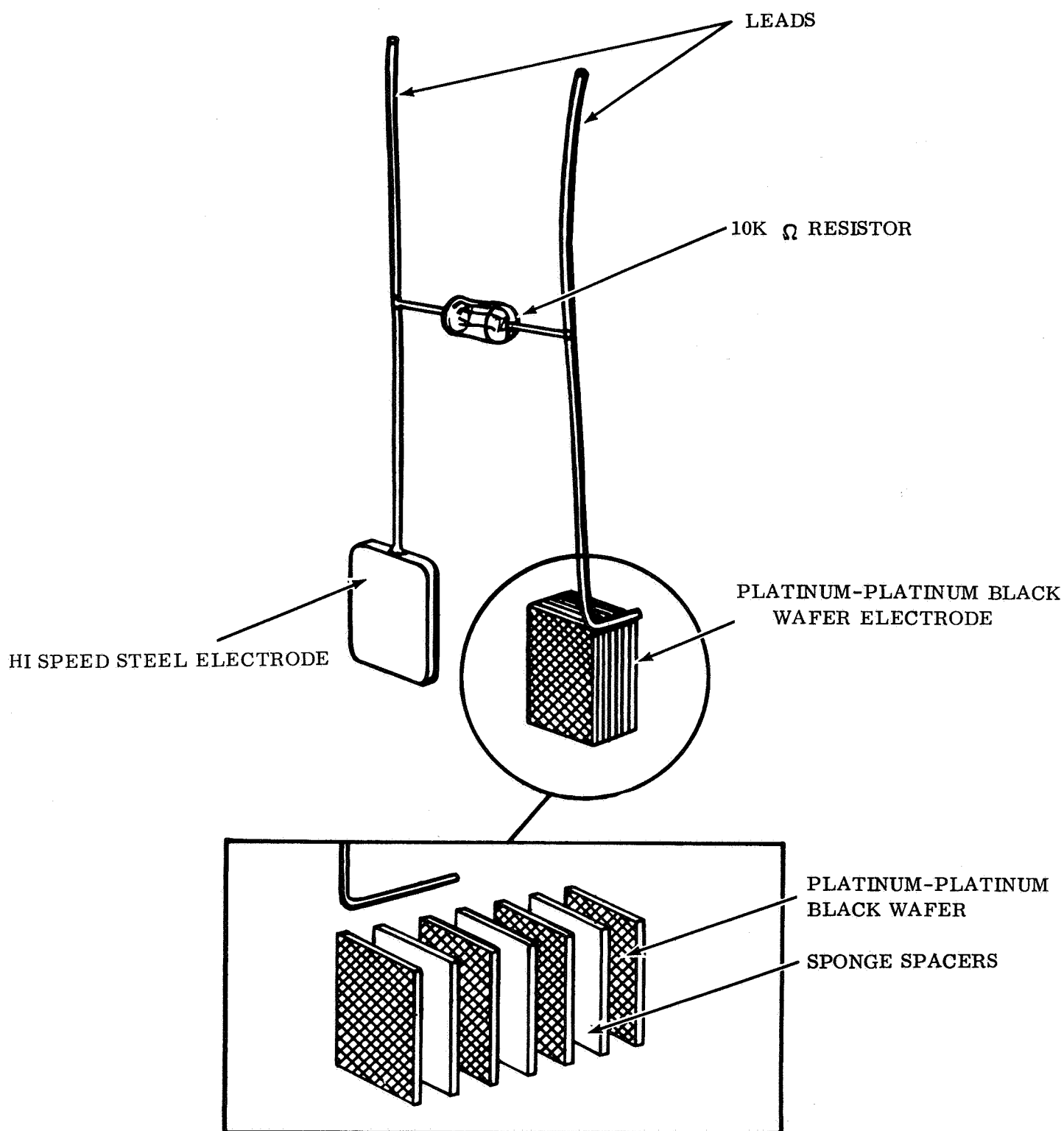


FIGURE 2



Roy and Wehnert (1966) have reported on keeping the heart alive with a biological battery powered pacemaker. They have been investigating various materials for implantation in addition to the platinum platinum black and high speed steel that was reported earlier. Silver and silver chloride have proved most consistent in potential developed and capacity as cathodes. Pure zinc, aluminum, iron, carbon or mild steel have been studied as anodes. They report that zinc appears superior to the others although Racine (1966b) reports aluminum as having some advantages in higher voltage and smaller weight loss. This might be primarily because zinc enters into the galvanic reaction rapidly. This can be established by examination of Faraday's Law of Electrolysis. This law states, in effect, that to produce a battery of one ampere-hour capacity one equivalent weight of material is liberated in each electrode. This predicts approximately how much material will be used in converting chemical energy to electrical energy for any battery capacity. It is implied that the energy production is the result of a galvanic reaction. This law cannot take into account losses to the metal electrode occurring because of natural corrosion which also occurs (Racine, 1966a). A battery was designed consisting of silver chloride and zinc electrodes which operates well in the body and produced one volt at up to 10 milliamps (10 ma). This power source uses its own depolarizer and chloride, and uses the body fluids as an electrolyte. This type of battery has been implanted in dogs and rabbits for periods of up to nine months without causing any ill effects. Other studies have indicated that large quantities of zinc can be tolerated by animals with no apparent ill effects. Roy (1966) observes that the galvanic reaction between the silver chloride and zinc produces a cloudy fluid within the sac of the encapsulating tissue, which is absorbed by the body. In general, the output measured by these investigators has been consistently higher than that obtained by Reynolds and/or Konikoff. The apparent reason is the enhanced galvanic reaction occurring on zinc because of the fact that zinc is at a much higher position on the electromotive series than iron or stainless steel.

### III. MOTION CONVERSION TO ELECTRICITY

The application of the piezoelectric effect in crystals has proven to be a rewarding investigation towards the possibility of using the body as a source of energy. Piezoelectricity is that generated in certain materials, usually crystals, when they are stressed. This is a convenient way to convert mechanical energy to electrical. (An example of the application of piezoelectricity is in a phonograph pickup.) The most widely used piezoelectric crystals are made from ferro-electric ceramics which are polarized with an electric field. They are easy to fabricate into large or small shapes and are highly sensitive. If two slabs of materials are cemented together to form a laminated cantilever beam, a piezoelectric bimorph is formed. The bimorph improves the electrical output because as the beam is bent, one of its halves goes into compression, the other into tension. The two halves are connected electrically so that their piezoelectric outputs add either in series or parallel, depending on the impedance desired. Thus the output may be doubled from a given bending moment.

Several locations within the human body are in rhythmic motion. As examples, consider the heart, rib cage, diaphragm, and

various blood vessels. All exhibit a rhythmic expansion and contraction. Myers, Parsonnet, Zuker, and Lotman (1964) have devised an electronic pacemaker in which the sole power source was two sheets of a ceramic bimorph placed on each side of the aorta of a dog, Figure 3. The expansion and contraction of the aorta bent the sheets and generated the electricity. The two sheets of material (each  $1\frac{1}{4}$  by  $1\frac{1}{2}$  inches) were placed in a hinged clamp and encapsulated in silicone rubber. The output of the crystals was rectified in a voltage doubler circuit and was then applied to the circuit of a pacemaker. Successful pacing of a dog with surgically induced heart block was accomplished. Myers *et al.* speculate that a possible limit to the long term use of these devices is fatigue that could cause the crystals to crack at the point where they are clamped. Most previous applications of bimorphs of this type have been in phonograph pickups in which no fatigue problems were encountered, however, the use of these transducers is so different that this experience is probably not applicable. It would appear, as Myers *et al.* point out, that the stress on these plates is probably sufficiently low not to cause problems. However, long term studies must be conducted.

Enger and Klain (1966) have also experimented with biological powered miniature cardiac pacemakers. Their system also involved the use of piezoelectric bimorphs. Their work indicates a refinement to the state-of-the-art such that it is now possible to design and construct a cardiac pacemaker and power source (bimorph) having dimensions of  $5.4 \times 1.4 \times 0.75$  cm and  $3.75 \times 1.87 \times 0.05$  cm respectively. Their experiments, which resulted in successful pacing, were conducted on animals for two months with the bimorph sutured to the left ventricle within the pericardial sac. The initial voltage level generated by the crystals in this experiment was  $1\frac{1}{2}$  to 3 volts. They do point out that one area of difficulty still remains. This concerns itself with the selection of an encapsulating material that will not permit the eventual inflow or diffusion of the interstitial fluids. Silicone rubber or silastic that has been almost universally used with implantations, will, with time, become relatively spongy and permit the diffusion of fluid into the electronic circuitry resulting in the shorting of the system.

Ko (1966) has described a piezoelectric energy converter in which stress fatigue is guarded by mechanically changing the pivot point for large excursions. He describes a  $2 \times 5 \times 1$  cm unit having 160  $\mu$ watts output at 4 volts. The crystal vibrates within a sealed chamber in a resonant mode. By using the capacitance of the crystal itself as part of a voltage doubler circuit higher voltages are achieved.

Myers *et al.* report on another application of piezoelectric bimorphs. Any pacemaker is basically an escapement, that is, input energy is stored and then released periodically to the heart at the correct rate. It would therefore seem natural to use a clockwork mechanism for the energy storage device. Unfortunately, actual self winding watch mechanisms have an energy output far too small to be used to power a pacemaker, although a device was developed by the Bulova Watch Company that works along similar principles. This mechanism was designed to absorb the energy available from diaphragm movement (at the rate of about twenty per minute) as the winding force. This requires a longer energy storage period than do the direct electronic devices described

# SCHEMATIC DIAGRAM CERAMIC BI MORPH APPLICATION

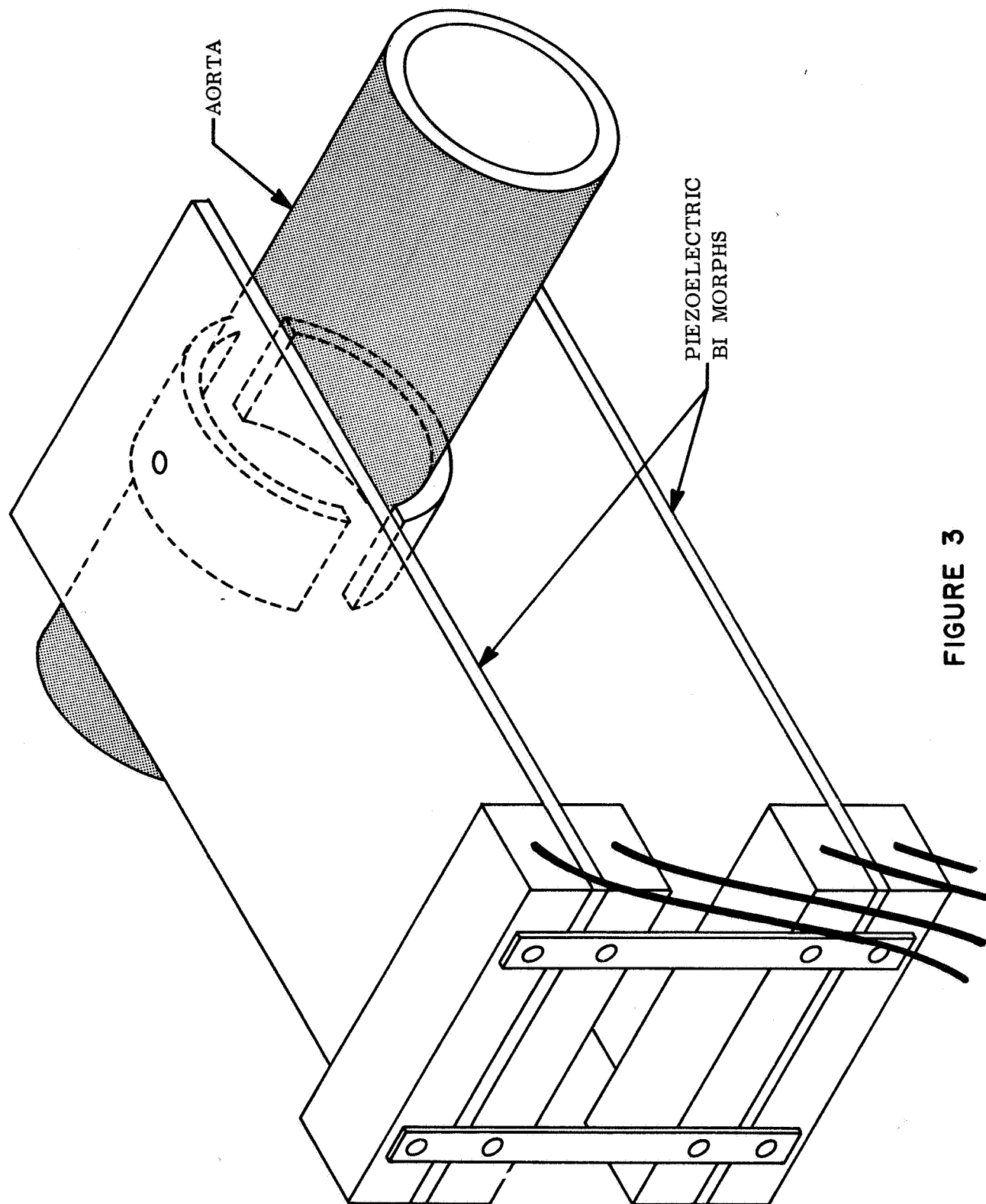


FIGURE 3

earlier. Winding movement from the diaphragm keeps a spring wound, which in turn operates a cam through a series of gears. A cam follower strikes a set of piezoelectric crystals. The impact produced the desired output pulse which was passed through a rectifier and impedance-matching transformer to the heart. *In vitro* experiments conducted with this type of device resulted in a pulse that was sufficient to produce ventricular contractions.

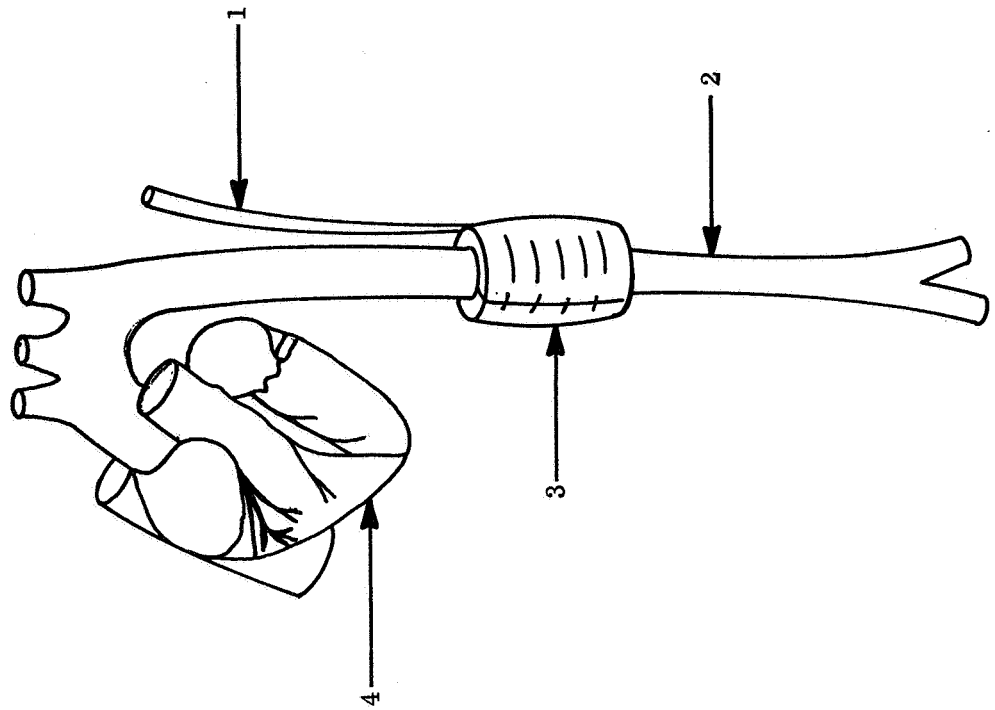
#### IV. USE OF SKELETAL MUSCLE POWER

Some surgical experimentation has been conducted by Kantrowitz, Kusserow and Clapp wherein by ingenious application of surgical skills they used selected muscles to serve as an auxiliary ventricle to power a blood pump directly and continuously over extended periods of time.

Kantrowitz (1960) conducted experiments on dogs wherein the diaphragm was divided in the mid-line and the left hemi-diaphragm was dissected from its peripheral attachments. Its major blood supply and left phrenic nerve were not disturbed. In one group of experiments, this fan shaped leaf of diaphragm was sutured around the heart so that its muscle fibres ran transversally to the long axis of the ventricles. In the second group, the hemi-diaphragm was folded into a rectangular shape with the muscle fibres running in a long axis. This muscle mass was then wrapped around the mobilized distal thoracic aorta so that its fibres ran perpendicular to the aorta, Figure 4. In both series, two silver wire electrodes were attached to the left phrenic nerve and brought out to a terminal strip. An electronic stimulator was attached to the left phrenic nerve terminal strip. The electric stimulus was supplied throughout systole in the first group of experiments and during diastole in the other experiments. In the case where the diaphragm was sutured around the heart, the experiments resulted in little if any improvement in the arterial pressures. In the experiment in which the thoracic aorta was wrapped by a portion of the diaphragm, a significant rise in diastole pressure was found. The work of the heart in delivering its stroke volume of blood to the aorta could therefore be eased by this surgical technique. Here the diaphragm muscle was doing a portion of the work that is normally reserved for the left ventricle.

Kusserow and Clapp (1964) investigated the use of skeletal muscle to biologically power a blood pump. They selected the easily accessible quadriceps femoris muscle. The motor nerve and tendon were first isolated and the tendon was then divided below the patella, the muscle being left intact *in situ* in other respects. They then coupled the muscle tendon to a pump using multiple strands of heavy suture. The pump, which was entirely external, consisted essentially of an elevated fluid reservoir with connecting tubes and a small spring loaded diaphragm pump with flap valves to insure unidirectional flow. The pump was driven by the contraction of the muscle during pump systole and recoil of the pump lever spring during diastole. Brief tetanic contractions of the quadriceps were produced by periodic indirect stimulation through its motor nerve. The stimulating electrodes consisted of multiple strand stainless steel wires of the type used with cardiac pacemakers. Results showed that the vigorous effective contractions generally persisted

# SCHEMATIC DIAGRAM UTILIZATION OF MUSCLE POWER



- 1- PHRENIC NERVE (ekg, TIMING, STIMULATING)
- 2- DISTAL THORACIC AORTA
- 3- LEFT HEMIDIAPHRAGM
- 4- HEART

FIGURE 4

without grossly observable diminution of the contractile force or pump output throughout each of the experiments, which lasted as long as eight hours. It was noted, however, that there was cellular injury of both a chemical and morphologic nature as a result of the particular condition of the experiment. The authors suggest further studies, especially those directed to finding a more optimal pattern of stimulation appear warranted.

## V. FUEL CELLS

Unlike batteries which are provided with internal chemical energy storage facilities, fuel cells are supplied continuously with reducing and oxidizing agents from the outside.

Basic internal ingredients are metallic electrodes at whose surface the half cell reactions occur, involving the removal or supply of free electrons via the metal.

The cell consists of external supplies of gaseous hydrogen as reductant and gaseous oxygen as oxidant in conjunction with the internal electrodes. The removal or supply of free electrons makes it possible to have the valence electrons of the reductant do the work before they are captured by the oxidant. Electrical energy is derived from the simultaneous oxidation of the material at the anode and reduction of the cathode material accompanied by ionic mass transport through the electrolyte. Electron flow is from the negative electrode (anode) through the external circuit to the positive cathode. The rate of water formation from  $H_2$  and  $O_2$ , is proportional to the electric current load.

A biochemical fuel cell may be defined as a system in which the reductant, oxidant or catalyst is constantly made available to the electrochemical environment as by the metabolic activity. However, using the oxidation-reduction potentials of body fluids appears justified for further study, since evidence from bacterial fuel cells is overwhelmingly in favor of extra-cellular reactions. There is thus the possibility of designing a system capable of performing this function in the mammalian organism.

Cahill, Nash, Neville and Van Der Grinten (1962) have considered the problem and reasoned that although there are several possible sites of implantation, the obvious are the abdominal and pleural cavities, the bloodstream, subcutaneous tissue and intestines. The factors necessary for implantation are as follows:

- (a) Correct oxygen tension, i.e. high for oxygen electrode, low for fuel electrode.
- (b) Continuous supply of necessary ingredients, i.e. fuel, oxygen, enzymes, electrolytes, solutions.
- (c) Lack of interference with normal body physiology.
- (d) Practicality of surgical approach and ease of application to the problem at hand.

- (e) Stability in long term experiments, i.e. avoidance of clotting in blood, fibrosis in tissues or abdominal or pleural cavities.
- (f) Similarity between experimental animal and human site environment.

Practical aspects suggested that the most desirable site for implantation would be the lumen of the large colon, probably at the cecum. There would be less problem with fibrosis, than there would be in the subcutaneous tissues. Implantation in the abdominal cavity would probably also result in fibrosis and peritoneal reaction, and the amount of free fluid available is very limited and might serve as a limiting feature. Inside the lumen of the large colon, the oxygen tension is virtually nil, there are abundant amounts of *E. coli* present which are actively reproducing and metabolizing. There is an alkaline pH and adequate enzyme activity is provided by the *E. coli*. Oxidation and reduction reactions also occur in relation to digestion and absorption of foods by the body's own enzymes.

The fuel electrode could be placed in the colonic lumen in the form of a platinum lead-out wire to a thin 10 x 1 cm x 1 mm millipore membrane sac into which dendritic carbon particles could be placed to provide electrical conduction. *E. coli* would grow in the sac as the millipore opening would permit the bacteria, glucose and electrolytes to enter and leave the sac easily. The waste products would also have free access. The carbon particles would remain in suspension and their size would not permit their loss. The surface area of the fuel electrode would be approximately 20 cm<sup>2</sup> (2 sides) and this would permit the production of an appreciable amount of current. The connections to the fuel and oxygen electrodes could be made by Teflon covered wires which would reduce tissue reaction. The problem of plugging the pore openings by the liquid caecal stool may be reduced by proper selection of pore size. An alternative method would be to implant foils, ribbons or chain-mail meshes of thin platinum into the lumen of the cecum.

The oxygen electrode in its simplest form can be merely two platinum black electrodes inserted into the blood stream, Figure 5, however, it was anticipated that this would be a potential source of blood clotting. A more sophisticated design is shown on Figure 6.

Unfortunately, no *in vivo* measurements are available from this investigation. Several *in vitro* measurements that are the result of a highly idealized simulation have been obtainable. Consequently, although scientifically intriguing, implanted fuel cells are far from being reduced to practice.

## VI. CONCLUSIONS

A survey has been conducted into several approaches taken to use the body as a source of power for implanted devices. By far the foremost use is at present to power implanted electronic cardiac pacemakers. Here the solution is a function of the circuitry design.

# IMPLANTED FUEL CELL SIMPLE ARTERIO-VENOUS SHUNT WITH SHINY PLATINUM ELECTRODES

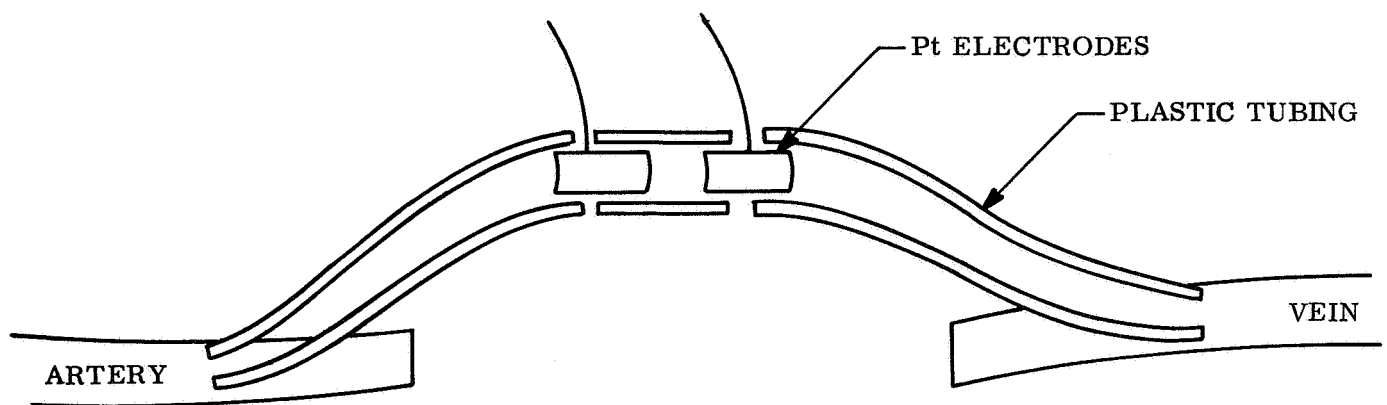


FIGURE 5



# IMPLANTED FUEL CELL ARTERIO VENOUS SHUNT OXYGEN ELECTRODE

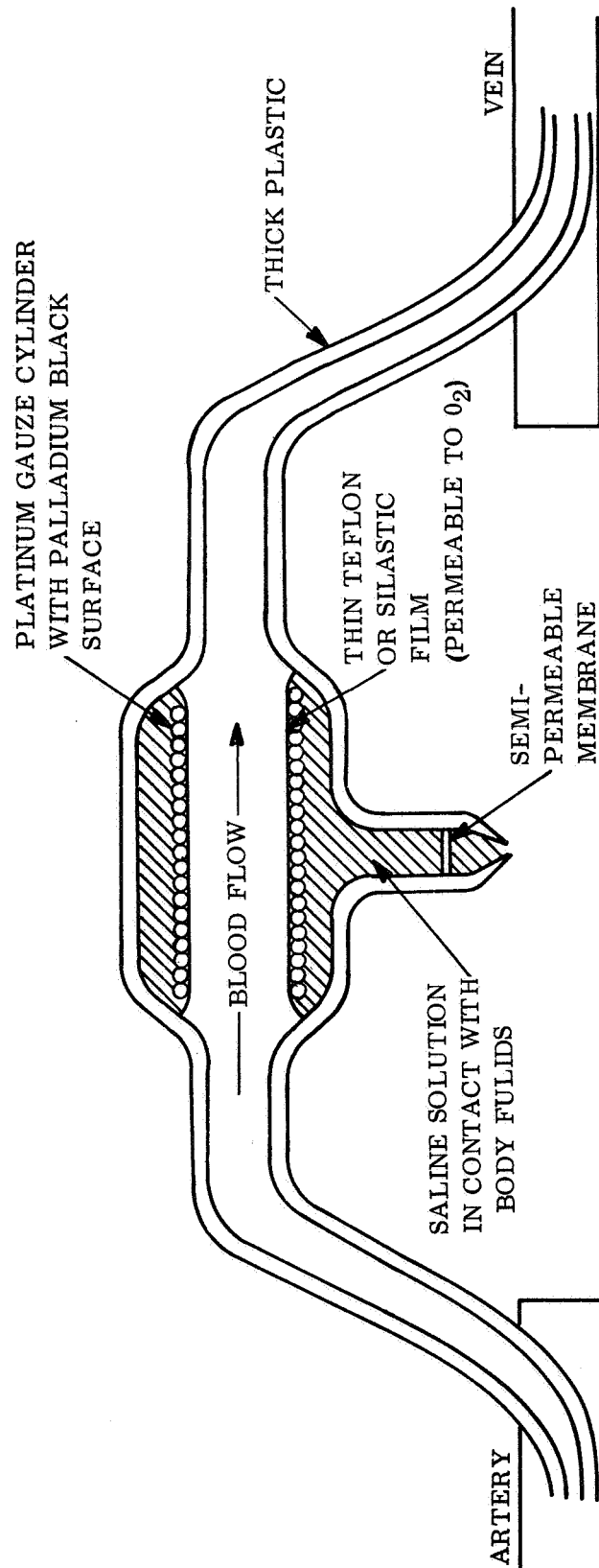


FIGURE 6

Although sufficient power (greater than 300  $\mu$ watts) can be achieved from the bioelectric potentials, the voltage level is quite low (about 0.5V). Thus, unless a voltage step-up transformer is included in the design, the transistor cannot be used efficiently, requiring use of tunnel diodes. Here a simple, static, relatively small inverter for low-voltage DC inputs can be designed which should prove reliable. Racine and Massie (1962) however, developed their pacemaker circuit including the step-up transformer, and achieved satisfactory transistor service. They realized a fifty percent transfer efficiency and had sufficient power to operate the pacemaker. Bioelectric potentials, when obtained at sufficiently high voltage, may be successfully applied to powering pacemakers as well as transmitters.

The use of the ceramic bimorph appears particularly suitable for service as the power supply for an implanted pacemaker. The measured voltage levels greater than 1.5 to 3 volts obviously simplify the circuitry design. Another advantage of the piezoelectric concept is that no galvanic reaction occurs within the immediate area of the implant. However, the problem area of crystal fatigue which may be the ultimate cause of failure exists. The bimorphs are somewhat larger than electrodes and are in constant contact with pulsating tissue thus causing potential problems because of abrasion and their size.

The use of musculature as a power source appears to be a highly specialized approach in the hands of a skilled surgeon. Widespread use is not yet indicated.

Implanted fuel cells, while theoretically interesting, are still in the stage where problems are concerned with physiological acceptance. In addition, many electrochemical problems still remain to be resolved. Until considerably more research is conducted on implantable fuel cells, this approach must remain impractical.

Table II presents a recapitulation of these conclusions and ranks the techniques based upon several criteria. As is shown, the Bioelectric Potentials are ranked first on two factors:

- a) Simplicity of Implant, and
- b) Expected Life.

## VII. RECOMMENDATIONS FOR FURTHER STUDIES

It is apparent as a result of this survey, that a number of unknowns are present in each of the four approaches described as means for using *in vivo* energy. This is true in spite of the fact that two of the techniques, BEP and Piezoelectricity, are in limited practice. It appears justified to continue investigations into these and perhaps other approaches in order that the best design is achieved.

To this end the following research studies are strongly recommended.

TABLE II

RANKING OF *IN VIVO* ENERGY SOURCES

METHOD	POWER LEVEL	LIFE EXPECTANCY	PRESENT STATUS <sup>2</sup>				PRINCIPAL PROBLEMS	APPLICATIONS	TOTAL POINTS <sup>1</sup>	RANKING
			1	2	3	4				
Bioelectric Potentials	≤1 mw @ 0.5 V	∞	X	X	P <sup>3</sup>		Implant Reactions Electronic Cir- cuitry	Pacemakers Stimulators Telemetry	8½	1
Piezoelectric Conversion	≤1 mw @ 1-6 V	2 years	X	X	X		Implant Reactions Fatigue Failures Potting Leaks	Pacemakers Stimulators Telemetry	8	2
Fuel Cell	>1 mw @ 0.5 V	2-3 years	X				Tissue Reactions Requires Break- through	Pacemaker Stimulators Telemetry Art. Heart	5½	3
Muscle	<25 μw @ ≈0.1 V	∞	X	P			Surgery Tissue Failure Necrosis	Ventricular assists Stimulators	4½	4

<sup>1</sup>Point System: Power Level: 1-5 pts. considering power and volt level  
Life Expectancy: 1 pt./year, 5 pts. max.

<sup>2</sup>Present Status: 1. Research & Development - 1 pt.  
2. Feasibility Demonstrated - 2 pts.  
3. Experimental Application - 3 pts.  
4. Hardware - 4 pts.

Principal Problems: One pt. off for each problem  
Ranking: Max. point score

<sup>3</sup>P = Partial

## 1. Bioelectric Potentials

- a) Studies on the mechanisms of energy production.
- b) Extended studies of implanted electrode systems to investigate power output and tissue reaction for one year or longer.
- c) Investigations aimed at increasing power output by selection of electrode materials, size and/or configuration.
- d) A study to determine the maximum power output that can be achieved without incapacitating the host animal.
- e) Electronic circuitry studies to best utilize the power availability at the relatively low voltage level.

## 2. Piezoelectric Power

- a) Long term studies *in vivo* to establish possible intolerance problems and fatigue failures.
- b) Investigations in depth to resolve the encapsulation problems.
- c) Studies to determine best crystal materials.
- d) Application studies to determine the best approach for using the power, i.e. direct or indirect (escapements).

## 3. Musculature

- a) *In vivo* empirical study leading to suitable surgical procedure to eliminate tissue destruction.

## 4. Fuel Cells

- a) Studies for the selection of oxygen and fuel sources in the body.
- b) *In vitro* studies of an experimental fuel cell constructed of benign materials using the oxidant and fuel selected in (a) above followed by *in vivo* studies.
- c) Studies to select fuel cell materials of construction including membranes, electrodes, and catalysts.
- d) Investigation of methods for the implanting of fuel cell and its connections to the host.

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